



REMARKS/ARGUMENTS

I. NON-PRIOR ART MATTERS.

- A. The Office Action rejected claims 1-6 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims need only “reasonably apprise those skilled in the art” for their scope and be “as precise as the subject matter permits.”¹ The test of definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification. If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, §112 demands no more.²

A claim need not describe the invention, such description being provided by the specification’s disclosure section.³

Applicant has amended claim 1 as suggested in the Office Action.

The amended claim, in light of the specification, is not indefinite or incomplete.

II. PRIOR ART MATTERS.

- A. The Office Action rejected claim 1 under 35 USC 102(b) as being anticipated by Crawley. Applicant respectfully traverses this rejection.

A single prior art reference anticipates a claimed invention only if it discloses each and every claim element.⁴

¹ *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81 (Fed. Cir. 1986)

² *id.*

³ *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1 USPQ2d 1081 (Fed. Cir. 1986)

⁴ *Structural Rubber Prod. Co. v. Park Rubber Co.*, 749 F.2d 707, 223 USPQ 1264 (Fed. Cir. 1984)

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Applicant has amended claim 1 to include elements and limitations from claims 2 and 3.

As to amended claim 1, Crawley does not disclose a vacuum source connected to the space between the liner and the residual limb and to the space between the liner and the socket, wherein application of the vacuum source to the space between the liner and the residual limb lowers the partial water vapor pressure in the space, allowing water vapor to more readily pass through the osmotic membrane, and wherein application of vacuum to the space between the liner and the socket draws the residual limb and liner into total contact with the socket interior.

Claim 1 is therefore allowable.

B. The Office Action rejected claims 2-6 under 35 USC 103(a) as being unpatentable over Crawley in view of either Caspers '709 or Helmy EP 0870485. Applicant respectfully traverses the rejection.

The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness.⁵ If the Examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of non-obviousness.⁶

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.⁷

⁵ MPEP Sec. 2142.

⁶ Id.

⁷ Id. (emphasis supplied)

Applicant respectfully traverses the § 103 rejection because the office action has not established a *prima facie* case of obviousness.

Even if combined, the references do not teach all of the limitations of amended claim 1, upon which claims 4-6 are dependent. Claims 2 and 3 have been cancelled and their limitations incorporated into claim 1.

The references do not disclose a vacuum source connected to the space between the liner and the residual limb and to the space between the liner and the socket, wherein application of the vacuum source to the space between the liner and the residual limb lowers the partial water vapor pressure in the space, allowing water vapor to more readily pass through the osmotic membrane, and wherein application of vacuum to the space between the liner and the socket draws the residual limb and liner into total contact with the socket interior, and a means to maintain a vacuum in the space, in the presence of some leakage past the seal means.

Specifically, Helmy EP 0870485 is inoperable because the liner will conform to the residual limb at all times, by an interference fit, so that there is no space between the residual limb and the liner against which to draw a vacuum. Further, Helmy does not disclose application of vacuum to the space between the liner and the socket in such a manner as to draw the residual limb and liner firmly and totally against the socket interior. Instead, the patent discloses the use of shims between the liner and the socket. Without total contact between the residual limb and liner and the socket, the limb may swell into the space between it and the socket. Finally, Helmy does not disclose the use of vacuum to remove perspiration. The above was pointed out by the Applicant in the Specification at pages 3 and 4. (EP 0870485 claims priority to U.S. Serial No. 831,149, which is the application from which U.S. 5,888,230 issued.)

Specifically, Caspers '709 does not disclose a mechanism for maintaining vacuum in the presence of air leakage into the socket. This was pointed out by the Applicant in the Specification at page 4.

Furthermore, there is no suggestion in Crawley to make the combination with either Helmy or Caspers.



The Federal Circuit recently stated:

"The factual inquiry whether to combine references must be thorough and searching...It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with...The need for specificity pervades this authority."⁸

In the above-cited case, the Federal Circuit held that "the examiner's conclusory statements...do not adequately address the issue of motivation to combine."⁹ That is also the case in the instant application.

Claim 1 is therefore allowable.

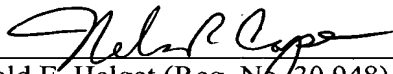
Claims 4-6 contain additional elements or limitations beyond allowable claim 1 and are also allowable.

Attached hereto is a marked up version of the change made to the claims by the current amendment. The attached page is captioned Version With Markings to Show Changes Made.

For the above reasons, Applicant respectfully requests the allowance of all claims and the issuance of a Notice of Allowance.

Respectfully submitted,

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⁸ *In re Sang Su Lee*, 277 F.3d 1338, 61 USPQ2d (BNA) 1430 (Fed. Cir. 2002)

⁹ *id.*



VERSION WITH MARKINGS TO SHOW CHANGES MADE

WHAT IS CLAIMED:

Claim 1 has been amended as follows:

1. (Amended) In an artificial limb for amputees who have a residual limb, the residual limb being encased in a liner, the residual limb and liner being inserted into [the] an artificial limb socket having a space between the liner and the socket, an apparatus for wicking away perspiration from the residual limb, the apparatus comprising: an osmotic membrane [encasing] to encase the residual limb and [lying] adapted for placement between the residual limb and the liner, thereby creating a space between the residual limb and the liner, the membrane being adapted to allow the passage of water vapor in one direction only, from the residual limb towards the liner[.], further comprising:

(a) a vacuum source connected to the space between the liner and the residual limb and to the space between the liner and the socket, wherein application of the vacuum source to the space between the liner and the residual limb lowers the partial water vapor pressure in the space, allowing water vapor to pass more readily through the osmotic membrane, and wherein application of the vacuum between the liner and the socket draws the residual limb and liner into total contact with the socket interior;

(b) a seal means for sealing the space; and

(c) a means to maintain a vacuum in the space, in the presence of some air leakage past the seal means.

Claims 2 and 3 have been cancelled.

Claim 4 has been amended as follows:

4. (Amended) The apparatus of claim [2]1, wherein the seal means further comprises a nonfoamed, nonporous polyurethane suspension sleeve for rolling over and covering the socket and a portion of the residual limb.



Claim 5 has been amended as follows:

5. (Amended) The apparatus of claim [3]1, wherein the vacuum source is a vacuum pump and the means to maintain the vacuum in the cavity is a regulator, and further comprising a power source for the vacuum pump and the regulator.

Claim 6 has been amended as follows:

6. (Amended) The apparatus of claim [3]1, wherein the vacuum source and the means to maintain the vacuum in the cavity further comprise a weight-actuated vacuum pump.